

August 26, 2002

Adrienne Kiley
Technical Contact
Propylene Carbonate/t-Butyl Alcohol
High Production Volume Committee
1250 Connecticut Avenue, N.W. Suite 700
Washington, D.C. 20036

Dear Ms. Kiley:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Tertiary Butanol posted on the ChemRTK HPV Challenge Program Web site on May 2, 2002. I commend The Propylene Carbonate/t-Butyl Alcohol HPV Committee for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The Propylene Carbonate/t-Butyl Alcohol HPV Committee advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Tertiary Butanol (t-Butanol)

SUMMARY OF EPA COMMENTS

The sponsor, Propylene Carbonate/t-Butyl Alcohol HPV Committee, submitted a test plan and robust summaries to EPA for t-butanol (CAS No. 75-65-0) dated April 10, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on May 2, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. (a) The physicochemical properties data provided by the submitter are adequate, except for water solubility. The submitter needs to provide quantitative data for this endpoint. (b) The biodegradation information provided by the submitter is incomplete. (c) EPA recommends that the submitter provide transport and distribution data using the Level III fugacity model.
2. Health Effects. EPA agrees with the submitter's proposal to conduct an enhanced OECD TG 421 study based on effects seen in the teratology studies. The submitter needs to address deficiencies in the robust summaries.
3. Ecological Effects. (a) The submitted ecotoxicity data for aquatic invertebrates are adequate. (b) EPA agrees with the submitter that testing is required for the algae endpoint. (c) EPA reserves judgement that further testing is required for the fish endpoint based upon existing fish toxicity data on t-butanol. The submitter should investigate the adequacy of the available data and, if adequate, submit the corresponding robust summary.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE TERTIARY BUTANOL (t-BUTANOL) CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The data submitted for melting point, boiling point, vapor pressure and partition coefficient are acceptable for the purposes of the HPV Challenge Program.

Water Solubility. In the robust summary the submitter indicates that this chemical is soluble in water, but provides no data. The submitter needs to provide quantitative data for this endpoint. EPA located a literature value of 1,000g/L.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA agrees with the submitter that a photodegradation estimation is not necessary. However, indirect photolysis can be estimated using AOPWIN. A stability in water test is indicated as a need in the test plan matrix, but the test plan text does not discuss this endpoint. EPA recommends the use of a Level III fugacity model instead of Level I.

Stability in water. The submitter in its test plan table (page 2) indicates that data are not available and that testing is recommended. However, in section II the submitter is silent on testing for this endpoint. The submitter needs to address this discrepancy.

Biodegradation. The biodegradation information provided by the submitter is incomplete. The submitter indicates on page 3 of its test plan that the authors of the biodegradation study did not provide test method details. Without these details the adequacy of the data cannot be evaluated. The submitter needs to provide a robust summary(ies) for the key ready biodegradation study(ies) cited. EPA reserves judgement on the adequacy of the biodegradation data until the submitter provides an adequate robust summary(ies). EPA has provided specific comments on how to enhance the robust summaries to the standard established in EPA's HPV Challenge Program Guidance at <http://www.epa.gov/chemrtk/guidocs.htm>.

Fugacity. The sponsor proposes to estimate the fugacity of these chemicals using a Level I EQC model. Although EPA had previously recommended the use of EQC Level I, this model is somewhat limited. EPA now recommends a level III analysis, which is more rigorous. The EQC and EPIWIN Level III models are acceptable. When developing its model the submitter should use measured data as inputs as much as possible. The use of default or estimated data may introduce uncertainties that then become magnified in modeling applications.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for acute, repeated-dose, genetic, and developmental toxicity for the purposes of the HPV Challenge Program. However, the submitter needs to address deficiencies in the robust summaries.

Reproductive/Developmental Toxicity. The submitter is proposing to conduct an enhanced OECD TG 421 study to investigate the effects of t-butanol on mating behavior, preimplantation, embryonic and fetal development, parturition, and postnatal survival and development until weaning. The proposal is based on effects seen in the teratology studies. Increased resorptions, increased fetal mortality, decreased fetal body weights and altered postnatal development were seen in the studies in rats and mice. EPA agrees with the submitter's proposal to conduct an enhanced OECD TG 421 study as detailed in the test plan based on the effects seen in the developmental studies.

Ecotoxicity (fish, invertebrates, and algae).

Data submitted on the aquatic invertebrate endpoint are adequate. EPA agrees with the submitter that testing is needed for the algae endpoint. EPA also agrees that the fish endpoint needs to be addressed. However, the submitter should consider data cited in the following publication: Giger, D.L., S.H. Poirier, L.T. Brooke, and D.J. Call (Eds.), Acute Toxicities of Organic Chemicals to Fathead Minnows *Pimephales promelas*, Vol. III. Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, 1986. If adequate, the data should be submitted in a robust summary.

Specific Comments on the Robust Summaries

Health Effects.

Acute Toxicity. In the key study (IRDC,1981) include mortality data and clinical signs per sex.

Reproductive Toxicity. The reported NOAEL and LOAEL in the Results section are for systemic toxicity that was observed in the 13-week repeated-dose toxicity studies. A NOAEL (40 mg/ml) for the reproductive organ toxicity for both sexes and both species need to be included in the results section. The units for dose levels conversion from mg/ml for rat and mice females need to be changed to mg/kg.

In the robust summary of on page 30, the NOAEL and LOAEL need to be specified and the dose unit needs to be corrected to mg/kg instead of mg/ml.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.